

ATTORNEY DOCKET NO.: JHU1900-1

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):

Andrew P. Feinberg

Art Unit:

Not Yet Assigned

Application No.:

10/629,318

Examiner: Not Yet Assigned

Filed:

July 28, 2003

Title:

METHODS FOR IDENTIFYING CANCER RISK

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

## TRANSMITTAL SHEET

Transmitted herewith for the above-identified application please find:

- 1. Information Disclosure Statement (2 pages);
- 2. Form PTO-1449 (3 pages);
- Twenty-Nine (29) References; and 3.
- 4. Return Receipt Postcard.

### **CERTIFICATION UNDER 37 CFR §1.8**

I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on this date, November 25, 2003, in an envelope addressed to: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Debbrah Reeves

(Name of Person Mailing Pape

November 25, 2003

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Page 2

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement, because it is being filed prior to the receipt of a first office action on the merits of the above-captioned application. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1355. A duplicate copy of this Transmittal sheet is enclosed.

Respectfully submitted,

Date: November 25, 2003

Emanuel J. Vacchiano

Registration No.: 43,964 Telephone: (858) 638-6754 Facsimile: (858) 677-1465

**USPTO CUSTOMER NUMBER 28213** 

GRAY CARY WARE & FREIDENRICH LLP 4365 Executive Drive, Suite 1100 San Diego, CA 92121-2133



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### INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. § 1.97, enclosed are references relating to the above-identified application. For the convenience of the Examiner, these references are listed on the attached Form PTO-1449 and copies are enclosed herewith.

It is respectfully requested that these references be considered in the examination of this application and their consideration be made of written record in the application file.

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FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office	Docket No. JHU1900-1 (104659-258)	Serial No.: 10/629,318
DEC 0 1 2003 15	Applicant(s): Andrew P. Feinberg	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date:	Group Art Unit: Not Yet
BY APPLICANT	July 28, 2003	Assigned

# **U.S. PATENT DOCUMENTS**

EXAM. INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA	5,552,277	09/03/1996	Nelson et al.			
	AB	5,786,146	07/28/1998	Herman et al.			· · · · · · · · · · · · · · · · · · ·
	AC	6,235,474B1	05/22/2001	Feinberg			

# FOREIGN PATENT DOCUMENTS

EXAM. INITIALS	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION (YES/NO)

# OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)

AD	Ravenel, J.D., et al., J. Natl. Cancer Inst. Vol. 93, 2001, Pgs. 1698-1703
AE	Rainer et al., <i>Nature</i> , Vol. 362, 1993, Pgs. 747-749
AF	Feinberg, A.P. and Vogelstein, B., "Hypomethylation Distinguishes Genes of Some Human Cancers From Their Normal Counterparts," <i>Nature</i> (Lond.), Vol. 301, 1983, Pgs. 89-92
AG	Feinberg, A.P., et al. "Reduced Genomic 5-Methylcytosine Content in Human Colonic Neoplasia," <i>Cancer Res.</i> , Vol. 48, 1988, Pgs. 1159-1161
AH	Ogawa, O., et al., "Relaxation of Insulin-Like Growth Factor II Gene Imprinting Implicated in Wilm's Tumour," <i>Nature</i> (Lond.), Vol. 362, 1993, Pgs. 749-751
AI	Steenman, M. J., et al., "Loss of Imprinting of IGF2 is Linked to Reduced Expression and Abnormal Methylation of H19 in Wilms' Tumour, <i>Nat. Genet</i> , Vol. 7, 1994, Pgs. 433-439

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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AJ	Uegima, H., et al., "Hot-Stop PCR: a Simple and General Assay for Linear Quantitation of Allele Ratios," <i>Nat. Genet.</i> , Vol. 25, 2000, Pgs. 375-376
AK	Sullivan, M.J., et al., "Relaxation of IGF2 Imprinting in Wilms Tumours Associated with Specific Changes in IGF2 Methylation," <i>Oncogene</i> , Vol. 18, 1999, Pgs. 7527-7534
AL	Moore, T, et al., "Multiple Imprinted Sense and Antisense Transcripts, Differential Methylation and Tandem Repeats in a Putative Imprinting Control Region Upstream of Mouse IGF <sup>2</sup> , Proc. Natl. Acad. Sci. USA, Vol. 94, November, 1997, Pgs. 12509-12514
AM	Issa, Jean-Pierre J., et al., "Switch from Monoallelic to Biallelic Human <i>IGF</i> <sup>2</sup> Promoter Methylation During Aging and Carcinogenesis." <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 93, October 1996, Pgs. 11757-11762
AN	Nakagawa, H., et al., "Loss of Imprinting of the Insulin-Like Growth Factor II Gene Occurs by Biallelic Methylation in a Core Region of <i>H19</i> -Associated CTCF-binding Sites in Colorectal Cancer," <i>Proc. Natl. Acad. Sci. USA</i> , January 16, 2001, Vol. 98, No. 2, Pgs. 591-596
AO	Lee, M.P., et al., "Loss of Imprinting of a Paternally Expressed Transcript, with Antisense Orientation to K <sub>V</sub> LQT1, Occurs Frequently in Beckwith-Wiedemann Syndrome and is Independent of Insulin-Like Growth Factor II Imprinting," <i>Proc. Natl. Acad. Sci. USA.</i> , Vol. 96, April 1999, Pgs. 5203-5208
AP	Cui, Hengmi, et al., "Loss of Imprinting of Insulin-like Growth Factor-II in Wilms' Tumor Commonly Involves Altered Methylation but not Mutations of CTCF or Its Binding Site <sup>1</sup> ," Cancer Research, Vol. 61, July 1, 2001, Pgs. 4947-4950
AQ	Takai, Daiya, et al., "Large Scale Mapping of Methylcytosines in CTCF-binding Sites in the Human H19 Promoter and Aberrant Hypomethylation in Human Bladder Cancer," Human Molecular Genetics, Vol. 10, No. 23, 2001, Pgs. 2619-2626
AR	Bartolomei, M.S., et al., "Epigenetic Mechanisms Underlying the Imprinting of the Mouse H19 Gene," <i>Genes &amp; Dev.</i> 7(9), September 1993, Pgs. 1663-1673
AS	Taniguchi, T., et al., "Epigenetic Changes Encompassing the <i>IGF2/H19</i> Locus Associated with Relaxation of <i>IGF2</i> Imprinting and Silencing of <i>H19</i> in Wilms Tumor," <i>Proc. Natl. Acad. Sci.</i> , Vol. 92, March 1995, Pgs. 2159-2163

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AT	Catchpoole, D., et al., "Mutation Analysis of <i>H19</i> and <i>NAP1L4 (hNAP2</i> ) Candidate Gene and <i>IGF2</i> DMR2 in Beckwith-Wiedemann Syndrome," <i>J. Med Genet</i> , 37(3) March 2000, Pgs. 212-215
AU	Nishihara, S., et al., "Multipoint Imprinting Analysis in Sporadic Colorectal Cancers With and Without Microsatellite Instability," <i>Int. J. Oncol.</i> , 17(2), August 2000, Pgs. 317-322
AV	Hofmann, W.K., et al., "Loss of Genomic Imprinting of Insulin-Like Growth Factor 2 is Strongly Associated with Cellular Proliferation in Normal Hematopietic Cells," <i>Exp. Hematol</i> , 30(4), April 2002, Pgs. 318-323
AW	Cui, H., et al., "Loss of Imprinting in Colorectal Cancer Linked to Hypomethylation of H19 and IGF2 <sup>1</sup> ," Cancer Research, 62, November 15, 2002, Pgs. 6442-6446
AX	Vu, T.H., et al., "Symmetric and Asymmetric DNA Methylation in the Human IGF2-H19 Imprinted Region, <i>Genomics</i> , 64(2) March 1, 2000, Pgs. 132-143
AY	Schoenherr, C.J., et al., "CTCF Maintains Differential Methylation at the <i>Igf2/H19</i> Locus," <i>Nat. Genet</i> , 33(1), January 2003, Pgs. 66-69.
AZ	Bell, A.C., et al., "The Protein CTCF is Required for the Enhancer Blocking Activity of Vertebrate Insulators," <i>Cell</i> , Vol. 98, August 6, 1999, Pgs. 387-396
ВА	Schneider, D. T., et al., "Multipoint Imprinting Analysis Indicates a Common Precursor Cell for Gonadal and Nongonadal Pediatric Germ Cell Tumors <sup>1</sup> ," <i>Cancer Research</i> , Vol. 61, October 1, 2001, Pgs. 7268-7276
ВВ	Uyeno, S., et al., "IGF2 But not H19 Shows Loss of Imprinting in Human Glioma <sup>1</sup> ," Cancer Research, Vol. 56, December 1, 1996, Pgs. 5356-5359
ВС	Yun, K., et al., "Analysis of <i>IGF2</i> Gene Imprinting in Breast and Colorectal Cancer by Allele Specific-PCR," <i>Journal of Pathology</i> , Vol. 187, 1999, Pgs. 518-522

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